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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,718	11/21/2001	James X. Hartmann	6818-26	3915

7590 04/07/2005

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,718	HARTMANN ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,10 and 12-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,10 and 12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 January 2005 has been entered.

2. Claims 4, 8, 9, 11, and 23-34 have been cancelled. Claims 1-3, 5-7, 10 and 12-22 are pending.

3. The text of those 35 US Codes not found in this action may be found in a previous office action.

Claim Rejections - 35 USC § 112

4. Claims 1-3, 5-7, 10 and 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing with respect to the "billfish specific antigen-containing sample" that is immobilized on the substrate. It is unclear if this "sample" is the same as the "test sample" recited in the preamble. If it is, the claim is confusing because "test samples" are normally not obtained or available until the time of the assay, therefore, a

ready-made device having an immobilized test sample is confusing. Furthermore, if it is a "test sample", how does one know for certain that it is a billfish specific antigen-containing test sample? And if one already know that it is, indeed, a billfish specific antigen-containing test sample, why does one need to perform an immunoassay to test for something that is already known. However, if the "sample" is not the same as the "test sample" and is more equivalent to a reagent sample containing billfish specific antigen, then the device is in operative because it cannot be used to further detect billfish specific antigen in a test sample as currently claimed.

Claim Rejections - 35 USC § 103

5. Claims 1-3, 5-7, 10, 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossi et al., (Hybridoma. Vol. 11, No. 3. 1992, pp. 333-338) in view of May (GB 2,204,398) for reasons of record which are reiterated herein below.

Rossi discloses a field-portable immunoassay kits for sailfish using a monoclonal antibody conjugated to an enzyme label. Rossi suggests that adaptation of the assay to a paper format would further reduce the assay time thus offering additional advantages to field test. See page 335-337.

Rossi differs from the instant invention in failing to teach a lateral flow assay device using nitrocellulose and various reagents that are conventional in a lateral flow assay device such as gold sol label.

May, however, teaches a kit comprising an assay device made of a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device containing a labeled specific binding reagent for an analyte which labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte which unlabeled reagent is permanently immobilized in a detection zone on the carrier material (page 3). The device contains a control zone is loaded with an antibody that will bind to the labeled antibody from the first zone. The control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation. Or as an alternative, the control zone could contain immobilized analyte that will react with excess labeled reagents from the first zone (page 9). May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). The metallic sols particles are in the range of about 20 nm in diameter (page 31).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the assay taught by Rossi to a paper lateral flow format such as taught by May because Rossi teaches that such adaptation reduces the assay time and therefore increases productivity. Furthermore, May teaches that their device may be adapted for a variety of analytes and provides the advantages of a device

suitable for use in the field that can provide analytical result that is rapid and requires a minimum degree of skill and involvement from the user leading to fewer errors.

Response to Arguments

6. Applicant's arguments files 28 January 2005 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Applicant argues that Rossi fails to teach or suggests a lateral flow immunoassay device, and May does not make up for the deficiencies of Rossi because May discloses a two-zone detection assay device whereas the instant invention is a single zone assay device. The device of May, as argued by Applicant, requires two antibodies, one of which is freely mobile in a moist sample ad the second is permanently immobilized. In contrast, the instant device requires that the *sample is immobilized* and a billfish specific antibody is added for detection of the antigen.

These arguments have been fully considered but are not persuasive. Rossi teaches all necessary reagents as well as the needs and motivation for detecting billfish antigens using a lateral flow assay format. May teaches the actual production of a lateral flow assay formats and further teaches that such a format can be adapted for any desired antigens. May also teaches the advantages of a lateral flow assay device and

kits comprising the same. Therefore, it would have been obvious to modify the device taught by May to detect billfish antigens such as taught by Rossi for the advantages taught by both references.

Furthermore, claim 1, as amended, requires a lateral flow substrate having two ends. The first end contains an immobilized billfish specific antigen-containing sample, and the second end has a structure for receiving a reagent solution. As discussed above, claim 1 is confusing with respect to the recitation of a "sample" and a "test sample". According to Applicant's argument, it appears that a "test sample" is immobilized on a substrate. However, the claim does not make clear whether the billfish specific antigens are directly immobilized onto the substrate, therefore, the transitional phrase "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps such as the addition or inclusion of other antibodies. Comprising is a term of art used in claim language, which means that the named elements are essential, but other elements may be added, and still form a construct within the scope of the claim. If this claim is broadly interpreted, the antigen taught by May is, in effect, immobilized to at least one end of the lateral flow device as soon as the antibodies that are immobilized on the device capture it. With respect to claim 1, the antibody solution is not recited as being an integral part of the device; therefore, it does not receive any patentable weight.

Claim 2 requires that the substrate be nitrocellulose. See May, page 5, lines 10-25.

Claim 3 requires that the nitrocellulose substrate be backed by plastic. See May, page 13, lines 33-36.

Claim 5 requires that the solution, in addition to comprising an antibody specific for the billfish antigen, further comprises a portion of the test sample. This claim does not add to the device of claim 1 because this solution, as explained above, is not part of the device.

Claims 6 and 7 require that the billfish antigen is sailfish serum albumin. See Rossi, pages 335 and 336.

Applicant argues that claim 13, for example, requires the detection of a billfish specific antigen in the lateral flow assay device using gold-conjugated monoclonal antibody. And further state that the novelty and importance of the instant invention is that the gold-conjugated monoclonal antibody detects bill-fish specific antigens among closely-related species of fish and that Rossi in view of May do not teach such an invention.

This argument is not persuasive. Claims 10 and 12-14 recite steps of using the device and thus are not considered positive limitation of the device. Specifically, claim 13 recites a gold-labeled antibody, not a *monoclonal antibody* as argued. Furthermore, the gold-labeled antibody is recited as being in a solution that is *not* part of the device of claim 1, but is *added* to the device of claim 1 during use. Therefore, this claim does not recite a position limitation of the device of claim 1. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the intended use recited in claims 10 and 12-14 does not result in a device that this different from the device taught by Rossi as modified by May.

The argument that the gold-conjugated monoclonal antibody detects billfish specific antigens among closely related species of fish is not persuasive since this is not specifically claimed. First, the instant claims are drawn to a device, *not* a method of detecting or distinguishing billfish specific antigens from other fish; second, the instant claims *do not* recite the use or presence of a *monoclonal antibody* that can accomplished the detection as argued.

Claim 15 requires a non-billfish specific antigen immobilized on the substrate. See Rossi, page 335 where bovine serum albumin was used as standards. Furthermore, May teaches the use of a control zone comprising non-analyte reagent immobilized on the substrate.

Claim 16 is directed to a test kit comprising a substrate similar to the substrate of claim 1, and a solution comprising an antibody that binds the billfish specific antigen. Rossi discloses such a solution at pages 335 and 336.

Claims 17 and 18 requires that the billfish specific antigen be serum albumin from sailfish, blue marlin and white marlin. See Rossi, page 335, *Assay of Billfish sera.*

Claims 19-21 requires that the antibody be labeled with gold sol particles having diameter between 10-40 nm. See May, page 5, lines 26-36.

Claim 22 requires non-billfish specific antigen immobilized on the substrate. Again, see Rossi, page 335 where bovine serum albumin was used as standards. Furthermore, May teaches the use of a control zone comprising non-analyte reagent immobilized on the substrate.

Because Rossi teaches the immobilized of billfish specific antigen to a substrate, and further teaches labeled antibodies specifically binding to these antigens, and because May teaches a lateral flow assay format, as well test kits comprising appropriate reagents, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assay device taught by May to includes reagents for a billfish assay because May teaches that their device may be adapted for a variety of analytes and provides the advantages of a device suitable for use in the field that can provide analytical result that is rapid and requires a minimum degree of skill and involvement from the user leading to fewer errors.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
4/11/05